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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,763	01/24/2002	Ernest B. Izevbigie	11428.0003.NPUS01 (JASU00)	9565

7590

07/08/2003

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 07/08/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/057,763

Applicant(s)  
Izevbigie

Examiner  
Christopher Tate

Art Unit  
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 6, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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### DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-13, in Paper No. 7 is acknowledged. Accordingly, claims 1-13 are presented for examination on the merits.

#### *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-6 and 9-13 are rendered vague and indefinite because they are outside the limitations of independent claims 1 and 8, from which they depend - i.e., claims 1 and 8 define an anti-neoplastic pharmaceutical composition (and method of preparing) which is obtained from *Vernonia amygdalina* leaves via the steps recited in claims 1 and 8 (via extracting with water then collecting the filtrate thereof) which represents a filtered crude water extract thereof. However, claims 2-6 and 9-13 are drawn to an anti-neoplastic composition (and methods of preparing) defined by various fractions and subfractions of a filtered crude water extract (i.e., obtained from the antineoplastic crude water filtrate of claims 1 and 8 via one or more chromatographic steps) and not to the actual filtered crude water extract or method defined by claims 1 and 8. Accordingly, claims 2-6 and 9-13 are rendered vague, indefinite, and confusing

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as they do not properly define the defined final product (or method) of claims 1 and 8 - i.e., a filtered crude water extract obtained from *Vernonia amygdalina* leaves (and a method of making the crude water extract), but instead define various fractions and subfractions (and chromatographic preparatory techniques) thereof. It is also unclear by the steps recited in claims 2-6 and 9-13 (including the final steps therein) as to what constitutes the final pharmaceutical product - which also causes these claims to be incomplete with respect the essential final/recovered chromatographic product/fraction obtained thereby (see, e.g., MPEP 2172.01).

***Claim Rejections - 35 U.S.C. § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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VETU Abstract), or over Almagboul et al. (Fitoterapia, 1988), or over Obatomi et al. (Phytother. Res., 1997).

A water extract obtained from the leaves of *Vernonia amygdalina* is apparently claimed.

Each of the cited references disclose a water extract obtained from the leaves of *Vernonia amygdalina* and, thus, appear to be identical to the presently claimed product (see VETU Abstract and entire documents of other cited references). The reference water extracts would inherently comprise a peptide of claim 7 since the claimed peptide(s) would be naturally present within *Vernonia amygdalina* leaves as well as inherently water-soluble.

In the alternative, even if the claimed filtered aqueous plant extract product is not identical to the referenced aqueous plant extracts with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced aqueous plant extracts are each likely to inherently possess the same characteristics of the claimed aqueous plant extract particularly in view of the similar characteristics which they have been shown to share including being water extracts obtained from the leaves thereof (e.g., if not expressly taught, a filtered vs. a non-filtered extract are not deemed to provide patentable distinction to the claimed invention because their bioactivities would not reasonably be expected to differ, and, further, it would be atypical in the herbal art not to remove the extraneous plant material from the final extract product via one of various conventional means including filtration - such other removal means being essentially equivalent

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to removal via conventional filtration). Thus, the claimed invention would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by each of the cited references, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

***Claim Rejections - 35 U.S.C. § 103***

Claims 1, 7, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ojukwu et al. (Bull. Anim. Health Prod. Afr., 1982), Almagboul et al. (Fitoterapia, 1988), and Obatomi et al. (Phytother. Res., 1997).

Each of the cited references teach a water extract obtained from the leaves of *Vernonia amygdalina* (see entire documents). The reference water extracts would intrinsically comprise a peptide of claim 7 since the claimed peptide(s) would be naturally present in *Vernonia amygdalina* leaves as well as intrinsically water-soluble. The adjustment of conventional working conditions (e.g., soaking the leaves in water then crushing them vs. crushing then soaking, filtering the water extract to remove extraneous leaf material therefrom) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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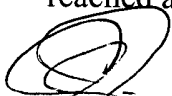
It is noted that the cited references used in the above art rejections do not teach that their plant extract compositions can be used in the manner instantly claimed (i.e., as an anti-neoplastic composition), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent to the reference extract compositions. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art compositions. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same or essentially the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103 (MPEP 2112).

### Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate  
Primary Examiner, Group 1654